

Report of the Consultation Meeting of the Revised International Health Regulations (IHR) for South American Countries Rio de Janeiro, Brazil – 5-7 April, 2004

I. GENERAL COMMENTS

The translation of the document into the Spanish was considered inadequate, compromising the clarity of the text and its review. It is proposed that PAHO/WHO (Pan American Health Organization, Regional Office for the Americas of the World Health Organization) review the translation of the next draft prior to its distribution to the Member States.

The structure of the document should be consistent: Parts, Chapters, and Articles should be organized by general and specific aspects.

The detailed contributions submitted by a number of delegations during the meeting will be included in the final report as attachments.

II. KEY ISSUES

1. **Core capacities.** Countries highlighted the need for the IHR to include a commitment by Member States to identify resources and timelines for the establishment of the core capacity which will enable full compliance with the IHR. Furthermore, specific guidelines are required for the assessment of existing capacities and to address gaps identified.
2. **Committees.** The role and composition of the Emergency Committee, Review Committee, IHR Advisory Panel and other entities included in the IHR draft must be specified. Also, balanced regional representation must be considered when convening Committees, as well as within the IHR Advisory Panel. In addition, countries demand the opportunity to be heard by the Emergency Committee before WHO announces an alert or an event that constitutes a Public Health Emergency of International Concern (PHEIC), as well as prior to the issuing of a temporary recommendation by the Emergency Committee.
3. **Notification/Information/Verification.** A number of delegations indicated that a list of diseases is needed, in addition to the decision instrument for the assessment and notification of events potentially constituting a PHEIC.

4. **Communications.** Communications between the National IHR Focal Point, the health administration, and WHO should be better defined. Direct communications between the National IHR Focal Point and WHO would not be acceptable without the prior authorization of the health administration.
5. **Decision Instrument.** The decision instrument for the assessment and notification of events that may constitute a PHEIC should be adjusted and tested to ensure a sensitivity that permits timely prevention and control interventions while minimizing the overload of the National and Global Alert and Response Systems.
6. **Ground Crossings.** It was proposed that designated ground crossings be subject to the same provisions as Airports and Ports set forth by Article 14.
7. **Measures.** Clearly define the level of responsibility of the institutions in charge of the implementation of public health measures relating to the goods, containers, and container loading areas.
8. **Charges.** A number of countries requested the right to charge a fee for vaccination, the issuing of international vaccination certificates, and/or prophylaxis.
9. **Definitions.** A significant number of the definitions need to be revised to ensure only one interpretation. In addition, it was noted that several relevant terms have not been included and all definitions must be those commonly used and recognized in the field of public health.
10. **Commitment by WHO.** Country delegations propose that an International Emergency Preparedness Plan be incorporated into the revised IHR. A number of country delegations recommended the establishment of a mechanism that allows for the resolution of discrepancies between the States and WHO.

III. General Considerations

Normative harmonization with other international organizations is recommended. In this regard, the need to have the concrete participation of the World Organization for Animal Health (OIE), the International Plant Protection Convention (IPPC) of the Food and Agriculture Organization of the United Nations (FAO), and Codex Alimentarius was emphasized since several countries participate in these organizations which already have several codes and health agreements.

The Secretariat of the meeting informed the participants that this process was in progress.

Article 2 - Purpose

The definition in itself as it reads in Spanish is considered very ambitious. It is proposed that it should read: **"...to reduce the risk of international spread of disease..."** instead of **"...provide security..."**.

Article 3 - Communications

Hierarchical conflicts may arise when implementing item 3 of article 3, as mentioned in the Key Issues section.

Country delegations have requested WHO to specifically indicate which of its offices should be notified of events that may constitute a PHEIC: Country Office, Regional Office, or WHO headquarters in Geneva.

Part II. Surveillance, notification, information, verification, and response

Article 4 - Surveillance

The following text is proposed:

"It is recognized that, in the event of a PHEIC, the information initially available may not allow for a comprehensive technical assessment of risk. Accordingly, recommendations issued by WHO and the national health measures applied should be based on all available, relevant information."

WHO recommendations and national measures shall be based on the best available information and scientific evidence and be proportional to the nature and scope of the PHEIC. WHO and the national health authorities will strive to obtain the necessary additional information to allow for an objective assessment of the risk and will review their recommendations or adopted measures accordingly and without delay following the notification of an event."

Article 5 - Notification

Item 2 does not clearly state that the sub-headings are exclusive. It is proposed that "or" be inserted between sub-headings, thus indicating that the health administration of the Member State would not necessarily be in agreement with the public dissemination of the event.

Article 7 - Information

It is proposed that goods containing biological, chemical, and radio-nuclear agents be subject to notification when they constitute a public health risk.

Item 2 could give rise to jurisdictional conflicts when a Regional or Sub regional Reference Laboratory, which is not a recognized Notification Center of the State, reports directly to the WHO.

Article 9 - Determination of a Public Health Emergency of International Concern

It is felt that it would not be advisable to include the phrase in item 2 "...WHO may make such information and recommendations available to the general public" since this is considered the responsibility of the health administration of each State. The text should read as follows ***"...the Health administration of each State, in coordination with the WHO ..."***

Article 10 - Response

A fifth item is proposed as follows: ***"WHO will create a contingency fund that will permit the financial support, in equipment or supplies, to countries that lack the necessary means for guaranteeing effective control and containment of events that may constitute a PHEIC."***

Part IV Points of entry

Article 13 - Health Administration

Sub-heading a) should reference article 14, item 1. It is suggested to correct article 13 to read "the points of entry and exit designated in articles 14 and 15"

Article 14 - Airports and ports

It is suggested that Article 16 (Health Authority) become Article 14, thus maintaining the hierarchical order.

In item 5 where it is mentioned that "These certifications may be subject to periodic review by WHO, in cooperation with the health administration", it is suggested that reference is made to a specific guide for the certification of ports and airports (to be prepared). It is also suggested that this guide include the established time intervals between reviews which, in any case, should not exceed five years.

Article 15 - Ground crossings

The phrase "Whenever the volume of the international traffic is sufficiently important" should be modified as follows: ***"When the volume of the international traffic is sufficiently important and when the epidemiological situation requires it"***.

It is proposed that the IHR text clearly indicate that ground crossings designated by the health administration pursuant to Article 15 are also subject to the provisions set out in item 5 of Article 14.

Article 16 - Health Authority

In item 3, it is proposed that the phrase "as required by these regulations..." be replaced by ***"when scientific evidence is available"***

Under item 5, the inclusion of "marine environment under its jurisdiction" as potential water contamination space is proposed.

Part V Public Health Measures

Chapter I. General Provisions

Article 17

It was proposed that reference be made to Article 23.

Chapter II. Special provisions for conveyances and conveyance operators

Article 21 - Conveyances at points of entry

Ground transportation is not included in this article. It is suggested that an item be added that addresses this means of transportation.

Chapter III. Special provisions for persons

Article 22 - Surveillance of the travelers

Where it states that "in the opinion of the health authority" a more precise definition is needed of what constitutes a suspect traveler. A clear description of what is meant by an immediate public health risk is also needed.

Chapter IV. Special provisions for goods, containers, and container loading areas

Article 24 - Goods in transit

The following addition is suggested: ***"...unless there is proof that they pose a public health risk, goods in transit shall not be subject to the application of measures under these Regulations"***.

It is suggested that a specific article be added stating that 'duty-free zones' that are exempt from customs and tax controls are not exempt from sanitary controls.

Article 25 - Containers and containing loading areas

- Consideration should be given to including chemical and radio-nuclear contamination, in addition to vectors.
- It is proposed that 'tires' be specifically mentioned in the text.
- It was suggested that a fourth item include the carrying out of inspections in accordance with WHO guidelines and that reference be made to existing guides.
- Regarding the spirit of the article, countries submit two proposals:
 - Carrying out of inspections through the establishment of programs to develop these measures
 - Screening of all containers and container loading areas

PART VI HEALTH DOCUMENTS

Article 27 - Certificates of vaccination or prophylaxis

The creation of an exemption certificate is proposed or a box providing for such an exemption on the vaccination certificate itself. The article should specifically mention said exemption(s).

Article 29 - Health Part of the Aircraft General Declaration

With regard to item 2, two proposals are submitted:

- To place the signature of the certificate for both ships and aircraft under the responsibility of the pilot in command or his designated representative on board;
- To accept the current drafting of the article this allows for the signature of either the commanding pilot or the operator.

PART VII CHARGES

Article 31 - Charges for medical examination, vaccination or other prophylaxis

A number of countries feel that the State should not bear the cost of these services as is set out in the article. One delegation proposes that only indigents or travelers suffering economic hardship should be able allowed to forgo the charges set by the health authority.

Article 36 - Rights of Persons

It is proposed that a clear definition is given for both "invasive" and "non-invasive" examination.

Article 37 - Migrants, nomads, seasonal workers or persons taking part in periodic mass congregations

A new article is proposed to address the physically disabled and the injured as follows: ***"The health administration shall facilitate the efficient and effective implementation of health measures under these Regulations, especially with regard to the physically disabled and injured. The said measures shall be applied preferentially and expeditiously to such persons."***

ANNEXES

ANNEX 1

A. Core Capacity Requirements for Surveillance and Response

Community level: It was noted that, in many countries, a number of the tasks set out in item 1 are the responsibility of health centers, especially as regards the detection of higher than expected levels of morbidity and mortality. It is proposed that the level that involves the community as a source of information be redefined.

In footnote 2, when essential information is defined, all the information that is mentioned in this box constitutes information obtained at health centers and not from the community.

First and intermediate public health response levels: It is proposed that the concept of "assessment" be reviewed and defined, indicating that it will be conducted on the strength of the best available scientific data.

National level: It is proposed that the 24 hour time period be replaced with 48 hour period (or more). Alternatively, the text should be modified to indicate that the assessment shall be carried out "*immediately*"

B. Core capacity requirements for designated airports, ports, and ground crossings

Item 2 c), regarding the phrase "...to provide for the isolation of suspect travelers who are not ill...", the countries submit two proposals:

- To clarify the sentence and specify which travelers who are not ill would be considered suspect; or
- To provide clear definition of a suspect case.

In Item 2 b) it is suggested that in addition to suspect travelers, the definition include suspect animals.

ANNEX 2

Regarding the decision instrument, it is suggested that if it is determined that the an event is not serious, it does not have public health impact which means that the algorithm should not be continued.

In terms of the implementation of the instrument, it is considered that because the algorithm is very sensitive, it can generate many unnecessary notifications with a low effectiveness. It is suggested that that it is based on country experience, such as what is carried out by MERCOSUR countries.

With regard to the questions in Annex II, examples should not be used, since in some instances there is no relationship between the example given and what it is intended to illustrate.

ANNEX 6

Item 4: Clarification is needed as to whether a signature or a signature *and* official stamp are required. In that same paragraph, it is proposed that the text be changed from medical practitioner or other clinician to "***competent health authority***" both in the annex and in the related certificate.

Items 5 and 9: It is proposed that the phrase be rewritten to read: "***The certificates shall be filled out in the official language of the country and in French or English.***"

Item 10: the countries submit two proposals:

- To maintain the text as is, making it clear that the section of the Armed Forces that issues such certificates should be duly accredited by the health administration
- To preclude the issuing of certificates by the Armed Forces.

It was suggested that the text specify that vaccines must come from WHO-accredited laboratories.

ANNEX 7

Item 2 must specify that only yellow fever vaccines from WHO-accredited laboratories should be used.

ANNEX 8

The title should include "***fluvial and lake***"

Under "Health questions", the note in question 3 (regarding unusual bleeding) should include: "***...accompanied or not by fever...***"

In column 8 of the table, the date of onset should include a footnote specifying that this refers to the onset of symptoms.

ANNEX 9

It is proposed that the current form be replaced by the form in "Appendix A", Annex 9, of the Agreement on International Civil Aviation 11th Edition- July 2002.